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10/010,448	11/07/2001	Sidney N. Wolfe	PP16166.003	5486

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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

9

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/010,448

Applicant(s)

WOLFE ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 4
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's species election without traverse of interferon  $\beta$  in Paper No. 8 is acknowledged. Claims 1-40 are pending in this application and are under examination as they pertain to interferon  $\beta$ .

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6-9, 26, 29-33, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/31479 (Platz et al).

WO 95/31479 teaches the production of a composition comprising interferon  $\beta$  and mannitol and the production of a dry powder by spray-drying of this mixture (Example 3, p. 12). WO 95/31479 thus teaches production of compositions of interferon  $\beta$  in liquid or lyophilized form: the result of spray-drying is the same as that obtained by lyophilization. WO 95/31479 thus anticipates the limitations of claims 1-4, 29-33 and 37. The concentration of interferon used was from .01% to 1%, or .01-1 mg/ml (p. 10, lines 21-22), anticipating the limitations of claim 6. The pH range taught is 2-9 (p. 10, lines 20-21) anticipating the limitations of claim 7. The inclusion of human serum albumin at a concentration of 2 mg/ml (2%) is taught on p. 13 in Example V, anticipating the limitations of claims 8 and 9. Recombinant interferon  $\beta$  is taught on p. 3, lines 23-29, anticipating claim 26.

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4. Claims 1, 2, 4, 5, 7-9, 26, 29-33, and 37 are also rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/31213 (Samaritani et al).

WO 95/31213 teaches the production of a composition comprising interferon  $\beta$  and mannitol on p. 2, lines 13-17, anticipating claims 1, 2, 4, 29-33, and 37. Isotonic mannitol is taught on p. 4, line 9, anticipating claim 5; an isotonic solution of mannitol is 5%. A pH range of 3-4 is taught on p. 2, lines 19-20, anticipating the limitations of claim 7. The inclusion of human serum albumin is taught on p. 4, line 34, at a level of 0.5 mg/ml (0.5%), anticipating the limitations of claims 8 and 9. Recombinant interferon  $\beta$ , as claimed in claim 26, is taught on p. 5, lines 11, 19, and 27.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 10-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/31479 in view of U.S. patent 4,808,705 (Ferris, 1989).

WO 95/31479 teaches as set forth above but fails to teach the low concentrations of mannitol claimed in claims 10-25. Mannitol at a concentration of 1.25% is taught by the '705 patent as beneficial for the ready resuspension of lyophilized protein (column 12, lines 24-30). It would have been obvious to one of ordinary skill in the art to combine the teachings of WO 95/31479 and the '705 patent to formulate compositions containing interferon  $\beta$ , mannitol, and albumin at the claimed concentrations and the claimed pH. One of ordinary skill would have been motivated to do so because WO 95/31479 teaches each of the claimed limitations except for the mannitol concentration, and the '705 patent teaches that the claimed concentration of mannitol can be successfully used. Thus one of ordinary skill would expect the substitution of lower levels of mannitol in the composition of WO 95/31479 to be successful as well.

7. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as unpatentable over WO 95/31213.

WO 95/31213 teaches as set forth above but fails to teach storage in syringes in either liquid or frozen form. However, it would have been obvious to one of ordinary skill in the art to store the compositions of WO 95/31213 in this fashion, because WO 95/31213 teaches storage "hermetically sealed under sterile conditions in a container suitable for storage prior to use", and a syringe would constitute such a suitable container.

8. Claims 34, 35, and 38-40 are rejected under 35 U.S.C. 103(a) as unpatentable over WO 95/31479 in view of U.S. patent 4,462,940 (Hanish et al., 1984).

WO 95/31479 teaches as set forth above but fails to teach removal of SDS and salts by chromatography and addition of albumin at pH 11.5-12. The '479 patent teaches that interferon  $\beta$  can be purified by removal of salt and detergent on sephacryl and TSK columns and

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subsequent addition of albumin at pH 11 (figure 1b). It would have been obvious to one of ordinary skill in the art to combine the teachings of WO 95/31479 with the '479 patent to further adjust the pH to physiological levels and add mannitol; one of ordinary skill would have been motivated to do so because WO 95/31479 teaches that this is a useful method of storage and it would *prima facie* obvious to combine a useful method of storage with a useful method of purification. It would further be obvious to one of ordinary skill to use a slightly higher pH than disclosed in figure 1b, because the '479 patent teaches pH 12 in column 5, line 67.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 1-9, 26-29, and 32-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims encompass "variants". There is no definition in the specification by which one of skill in the art could recognize what degree of variation was acceptable, and thus what molecules would be considered variants.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
August 6, 2008



JANET ANDRES  
PATENT EXAMINER